

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83607

MEDICAL REVIEW(S)

REVIEW OF RESUBMISSION - AMENDMENT

DATE COMPLETED: 1-23-74

ANDA #: 83-607

CO. NAME: Richlyn Labs. Inc.
Castor & Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 10-30-73; 11-2-73 and 11-9-73

TYPE OF SUBMISSION: Resubmission - amendment.

CLINICAL EVALUATION:

1. Review of Studies: The previously submitted statistical analysis of the performed bioavailability study is under review.

2. Review of Labeling:

a. Container labels: FPL is submitted for the following distributor:

The submitted bottle labels (100's and 1,000's of the 25 mg. tablet; 100's of the 50mg. tablet) are satisfactory.

b. Package insert: Not submitted in this amendment. The distributor will use Richlyn's insert.

CONCLUSION: The submitted container labeling for satisfactory.

RECOMMENDATION: The firm is to be so notified.

/S/

J. Bacsanyi, M.D.

REVIEW OF RESUBMISSION & AMENDMENT

DATE COMPLETED: 10-31-73

ANDA #: 83-607

CO. NAME: Richlyn Labs., Inc.
Castor & Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 10-17-73 (resubmission) and 10-22-73 (amendment)

TYPE OF SUBMISSION:

CLINICAL EVALUATION:

1. Review of Studies: the requested statistical analysis of the submitted bioavailability study is provided in the resubmission.

2. Review of Labeling:

a. Container labels: FPL is submitted for the following distributor:

It is satisfactory.

b. Package insert: Not submitted in this amendment. The distributor will apparently use the insert approved for Richlyn.

CONCLUSION: 1. A statistical analysis of the performed bioavailability study is submitted.
2. FPL for a new distributor is submitted and it is satisfactory.

RECOMMENDATION: 1. Refer the submitted statistical analysis to DCR.
2. Notify the firm that the labeling submitted for is satisfactory.

/S/

J. Bassanyi, M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 12-27-73

ANDA #: 83-607

CO. NAME: Richlyn Laboratories, Inc.
Castor and Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 9-25-73

TYPE OF SUBMISSION: Amendment

CLINICAL EVALUATION:

1. Review of Studies: Bioavailability study has already been performed - under evaluation by DCR.
2. Review of Labeling:
 - a) Container labels: FPL is submitted for one of the distributors of the drug: Interstate Drug Exchange, Plainview, L.I., NY 11803. The submitted labels are satisfactory.
 - b) Package insert: Not submitted in this submission. The firm will use Richlyn's insert.

CONCLUSION: The submitted label is satisfactory

RECOMMENDATIONS: The firm is to be so notified.

JS/
J. Bacsanyi, M.D.

REVIEW OF AMENDMENT

Date Completed: 10/1/73

ANDA # 83-607

Richlyn Labs, Inc.
Carter & Kensington Aves.
Phil. PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 8/24/73

TYPE OF SUBMISSION: Amendment for a new distributor:
Wolins Pharmacal Corp.
Melville, NY 11746

CLINICAL EVALUATION:

1. Review of Studies:

Bioavailability study has already been performed - under evaluation by DCR.

2. Review of Labeling:

a. Container labels:

The submitted FPL is satisfactory.

b. Package Insert: Not submitted in this submission.
Previously evaluated and approved.

CONCLUSION: The submitted FPL is satisfactory from a medical standpoint.

RECOMMENDATION: The firm is to be so notified.

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J. Bacsanyi, M/D.

REVIEW OF AMENDMENT

DATE COMPLETED: 8-28-73

ANDA #: 83-607

Richlyn Labs, Inc.
Carter and Kensington Aves.
Philadelphia, Pa. 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25mg. and 50mg.

DATE OF SUBMISSION: 5-14-73; 5-17-73; 5-21-73; 5-29-73; 6-1-73; 6-5-73; 6-22-73; 6-29-73;-
7-19-73

TYPE OF SUBMISSION: Amendments for new distributors.

CLINICAL EVALUATION:

1. Review of Studies:

The previously submitted bioavailability protocol has been evaluated by DCR.

2. Review of Labeling:

a. Container Labels: FPL is submitted for the following distributors:

1. (50mg tablets)
2. (ts)
3. The Interstate Drug Exchange, Inc. Engineers Hill, Plainview, L.I., N.Y. 11803
- 4.
- 5.
6. Spencer-Mead, Inc. Valley Stream, New York 11582
- 7.
- 8.

The label is not satisfactory. The main heading should be the name of the drug.

The rest of the labels are acceptable.

b. Package Insert: Not submitted in this submission. Previously evaluated and approved.

CONCLUSION: The container label for 1 should be revised. The rest of the labels are satisfactory.

RECOMMENDATIONS: Request revision of the containers label for one distributor: n.

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J. Baer, M.D.

CC
DOP-69
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BPD/emb/8-29-73

REVIEW OF ANDA

Date Completed: 3/12/73

ANDA #: 83-607
Richlyn Labs., Inc.
Castor & Kensington Aves.
Philadelphia, Pa. 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 3/22/73

TYPE OF SUBMISSION: ANDA

Clinical EVALUATION:

1. Review of Studies:

- A. Manufacturing information, ingredients etc. will be evaluated by the chemist.
- B. A ~~product~~ ^{pre-clinical} protocol for the required bioavailability is submitted.

2. Review of Labeling:

a. Container Labels:

FPL for the bottle containers is submitted, it is satisfactory.

b. Package Insert:

The submitted FPL is satisfactory.

CONCLUSIONS:

- 1. All the labeling is medically approvable.
- 2. A protocol for the required bioavailability study is submitted.

RECOMMENDATIONS:

Refer bioavailability protocol to DCR for evaluation.

/S/
J. T. Bacsanyi M.D.

4/19/73

REVIEW OF AMENDMENTS

DATE COMPLETED: 2-13-74

ANDA #: 83-607

CO. NAME: Richlyn Labs. Inc.
Castor & Kensington Ave.s
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 1-22-74

TYPE OF SUBMISSION: Amendments for new distributors.

CLINICAL EVALUATION:

1. Review of Studies: A bioavailability study has been submitted and is under review by DCR.

2. Review of Labeling:

a. Container labels: FPL is submitted for the following distributors:

These labels are satisfactory.

b. Package insert: Not submitted in this submission.
The distributors will use Richlyn's insert.

CONCLUSION: The submitted distributor labeling is satisfactory

RECOMMENDATION: The firm is to be so notified.

NOTE: This firm does not have an approved ANDA for Hydrochlorothiazide.
M. Seife, M.D.

JS/
J. Bacsanyi, M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 2-12-74

ANDA #: 83-607

CO. NAME: Richlyn Labs. Inc.
Castor & Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 1-22-74 and 1-28-74

TYPE OF SUBMISSION: Amendments for a new distributor:

CLINICAL EVALUATION:

1. Review of Studies: The previously submitted statistical analysis of the performed bioavailability study is under review.
2. Review of Labeling:
 - a. Container labels: FPL is submitted for the 100 and 1,000 tablet containers. They are satisfactory.
 - b. Package insert: Not submitted in this amendment. The distributor will use Richlyn's insert.

conclusion; The submitted distributor labeling is satisfactory.

RECOMMENDATION: The firm is to be so notified.

Note: This is not an approved ANDA

JS
J. V. Bacsanyi, M.D.

REVIEW OF SUPPLEMENTS

DATE COMPLETED: 8-5-77

ANDA #: 83-607/S-001 to S-012

CO. NAME: Richlyn Labs., Inc.
Philadelphia, PA 19124

APPROVAL DATE: 6-6-77

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 6-16-77; 6-30-77; 7-12-77

TYPE OF SUBMISSION:

1. Review of Studies: none submitted.
2. Review of Labeling: FPL is submitted for the following distributors -

S-008 R.A. McNeil Co., Chattanooga, TN 37416
(trade name - M-Zide)
S-009 Interstate Drug Exchange, Plainview, L.I., NY 11803
S-010 Spencer-Mead, Inc., Valley Stream, NY 11582
S-011 Wolins Pharmacal Corp., Melville, NY 11746

All these labels are satisfactory.

CONCLUSION: The submitted distributor labeling is satisfactory.

RECOMMENDATIONS: The firm is to be so notified.

/S/
G. Bacanyi, M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 3-1-74

ANDA #: 83-607

CO. NAME: Richlyn Labs., Inc.
Castor & Kensington Aves
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 2-6-74

TYPE OF SUBMISSION: Amendment for a new distributor:

CLINICAL EVALUATION:

1. Review of Studies: None submitted, none required
2. Review of Labeling:
 - a) Container labels: The submitted FPL (for the 100 tablet containers) is satisfactory. (Trade name:
 - b) Package insert: Not submitted in this submission. The distributor will use Richlyn's insert.

CONCLUSION: The submitted distributor labeling is satisfactory.

RECOMMENDATIONS: The firm is to be so notified.

1/3
J. Bacsanyi, M.D.

M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 4-12-74

ANDA #: 83-607

CO. NAME: Richlyn Labs., Inc
Castor & Kensington Aves
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 3-15-74

TYPE OF SUBMISSION: Amendment for a new distributor:

CLINICAL EVALUATION:

1. Review of Studies: None submitted - none required.

2. Review of Labeling:

a) Container labels: The submitted FPL for the 10 tablet containers is satisfactory.

b) Package insert: Not submitted in this submission. The distributor will use Richlyn's insert.

CONCLUSIONS: The submitted distributor labeling is satisfactory.

RECOMMENDATIONS: The firm is to be so notified.

/S/

J. Bacsanyi, M.D.

REVIEW OF AMENDMENTS

DATE COMPLETED: 7-31-74

ANDA #: 83-607

CO. NAME: Richlyn Labs., Inc.
Castor & Kensington Aves
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 5-23-74 and 5-30-74

TYPE OF SUBMISSION: Amendments for new distributors

CLINICAL EVALUATION:

1. Review of Studies: None submitted - none required.

2. Review of Labeling:

a) Container labels: FPL Is submitted for the following distributors -

- 1.
- 2.

All these labels are satisfactory.

b) Package insert:

Not submitted in this submission. The distributors will use Richlyn's insert.

CONCLUSIONS: The submitted distributor labeling is satisfactory

RECOMMENDATIONS: The firm is to be so notified.

J. Bacsanyi, M.D.

NOTE: Recommend that further distributor amendments not be approved until ANDA is approved. M. Seife, M.D.

REVIEW OF AMENDMENTS

DATE COMPLETED: 9-19-74

ANDA #: 83-607

CO. NAME: Richlyn Labs., Inc.
Castor & Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 8-7-74 and 8-22-74

TYPE OF SUBMISSION: Amendments for new distributors

CLINICAL EVALUATION:

1. Review of Studies: None submitted - none required

2. Review of Labeling:

a. Container Labels: FPL is submitted for the following distributors:

1.

2. Geneva Generics, Inc.

b. Package Insert: Not submitted in this submission. The distributors will use Richlyn's approved insert.

CONCLUSIONS: The submitted distributors labeling is satisfactory.

RECOMMENDATIONS: Approval for the Geneva Generics amendment should be refused. This was submitted after the company received our last letter, which requested suspension of submitting further amendments for new distributors.

/s/
J. Bacsanys, M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 12-12-74

ANDA #: 83-607

CO. NAME: Richlyn Laboratories, Inc.
Castor & Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Trade & Generic: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: Nov. 5, 1974

TYPE OF SUBMISSION: Amendment for a new distributor:

CLINICAL EVALUATION:

1. Review of Studies:

The bioavailability status of this application is under clarification.

2. Review of Labeling:

The submitted labeling for the 1,000 bottle container is satisfactory.

CONCLUSIONS: The submitted distributor labeling is satisfactory.

RECOMMENDATIONS: Approval for this amendment should be refused until the company answers our letter of August 9, 1974, regarding the bioavailability status of this drug.

/S/

J. Bacsanyi, M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 3-31-75

ANDA #: 83-607

CO. NAME: Richlyn Labs., Inc.
Castor & Kensington Aves.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 11-24-74, 12-31-74, 1-7-75 & 1-31-75

TYPE OF SUBMISSION: Amendments for new distributors

CLINICAL EVALUATION:

1. Review of Studies: A submitted bioavailability study was found unsatisfactory by DCR.
2. Review of Labeling: FPL is submitted for the following distributors:
 - a. Spencer-Mead, Inc., Valley Stream, NY 11582 (for the bottle of 100's)
 - c. Interstate Drug Exchange, Inc. Plainview, L.I., NY 11803
 - d. Spencer-Mead, Inc., Valley Stream, NY 11582 (for the bottles of 1,000's)
All this labeling is satisfactory

CONCLUSIONS: The submitted distributor labeling is approvable.

RECOMMENDATIONS: Withhold approval of these amendments since Richlyn hasn't clarified the status of bioavailability of this drug.

J. Bacsanyi, M.D.

4-1-75

REVIEW OF AMENDMENT

DATE COMPLETED: 11-14-75

ANDA #: 83-607

CO. NAME & ADDRESS:
Richlyn Labs., Inc.
Philadelphia, PA 19124

NAME OF DRUG: Hydrochlorothiazide 50 mg Tablets

DATE OF SUBMISSION: 6-27-75 and 7-3-75

TYPE OF SUBMISSION: Amendments for distributors

CLINICAL EVALUATION:

1. Review of Studies: A submitted bioavailability study was found unsatisfactory by DCR.
2. Review of Labeling:
 - a. Container Labels: FPL is submitted for the following distributors:
 1. R. A. McNeil Company, Chattanooga, TN 37416, Trade name: M-Zide

These labels are satisfactory

CONCLUSIONS:

1. The submitted distributor labeling is acceptable.
2. No response to our request for submission of bioavailability information.

RECOMMENDATIONS: Withhold approval until Richlyn responds to our request on the bioavailability of the drug.

/S/

J. Bacsanyi, M.D.